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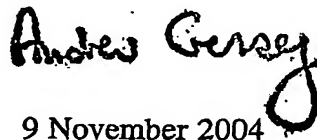
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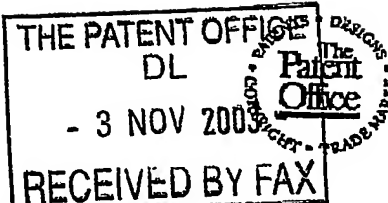


Dated

9 November 2004

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Patents Form 1/77

Patents Act 1977
(Rule 16)03NOV03 E849030-1 D00350
P01/7700 0.00-0325579.1

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
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NP10 8QQ

1. Your reference

MG/LAT/LW/P/25224.GB

2. Patent application number

(The Patent Office will fill in this part)

0325579.1

- 3 NOV 2003

3. Full name, address and postcode of the or of each applicant (underline all surnames)

MedTrade Products Ltd
Electra House
Crewe Business Park
Crewe
CW1 6GL

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

8288300001

4. Title of the invention

TOOTH-WHITENING COMPOSITION

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

WILSON GUNN M'CAW
41-51 ROYAL EXCHANGE
CROSS STREET
MANCHESTER
M2 7BD

Patents ADP number (if you know it)

7153927001 ✓

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
(if you know it)Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if

YES

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or

c) any named applicant is a corporate body.

See note (d))

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form.
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Continuation sheets of this form

Description

5

Claim(s)

Abstract

Drawing(s)

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

Date 03/11/2003

Wilson Gavin McLeod.

12. Name and daytime telephone number of person to contact in the United Kingdom

DR. LUCY TOVELL

0161 827 9400

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Tooth-Whitening Composition

The present invention relates to a tooth-whitening composition.

It is widely accepted that teeth become stained as a result of daily life. For example, exposure to any of cigarettes, tea and coffee stains the teeth. Clearly, the
5 more the teeth are exposed to these materials the greater the extent of staining of the teeth.

Recently, people are becoming even more interested in their appearance and the whiteness of their teeth has become an important concern for many people. As a result of this a number of tooth pastes now claim to have a teeth-whitening effect.
10 These toothpastes are, on the whole, abrasive and, due to short exposure times, have limited effects.

More recently, chemical formulations have become available which have a tooth-whitening effect. For example, WO 01/68045 discloses multilayer patches which utilise peroxide as an active whitening agent. The active material is associated
15 with a carrier material which is removed from the teeth following treatment.

WO 03/015656 refers to a delivery strip for an oral healthcare substance. The oral healthcare substance can be a whitening agent and the delivery strip is removed from the surface of the teeth following treatment.

These systems increase the contact time of the active material with the stained
20 teeth. However, the carrier material, which protects the gum areas from over exposure to the active material, can be uncomfortable for the user and awkward to remove once treatment is concluded. Therefore, it is desirable to provide an effective tooth-whitening composition that is sufficiently mild so as not to damage the tissue

surrounding the teeth, such that it can be applied without the need for a carrier material.

According to the present invention there is provided a tooth-whitening composition comprising a whitening agent characterised in that the composition is in the form of a water-soluble film.

Advantageously, the composition of the present invention is provided in the form of a water-soluble film such that no carrier material is required.

The film is applied to the surface of the teeth and, upon contact with saliva, begins to dissolve. The film is such that dissolution occurs over a period of time ranging from 30 seconds up to 120 minutes. Advantageously, this slow dissolution enables the film, and therefore the active ingredients contained therein, to contact the teeth for a sufficient period of time to effect tooth-whitening.

Surprisingly, following dissolution of the film of the present invention a coating is left on the teeth for hours after use, giving a gentle long term effect. The user is unaware of the presence of this coating.

Clearly the lack of a carrier material provides greater ease of use than currently available products as there is no carrier material to remove from the surface of the teeth following treatment. Furthermore, the amount of active ingredient that to which the user is exposed to controlled. This is in contrast to prior art systems, where the user may disregard the use directions and leave the carrier material, and therefore the active material, in contact with the teeth for too long. This is not a concern with the compositions of the present invention.

In addition to the whitening agent typically the film preferably comprises at least one film forming polymer, at least one plasticiser, and at least one filler.

Suitable film forming polymers for use with the present invention include any of the following: polysaccharides, polyvinyl alcohol, propvinyl pyrrolidone, and polyacrylic acid based polymers such as CARBOPOL[®] and mixtures and derivatives thereof.

- 5 The most preferred film forming polymers for use with the present invention are those derived from cellulose, such as carboxymethyl cellulose and hydroxyethyl cellulose.

The film forming polymer preferably constitutes from 10 to 95% w/w of the total composition.

- 10 Suitable plasticisers for use with the present invention include any of the following; Polyhydric alcohols such as glycerol, propylene glycol, polyethylene glycol, Sugar syrups such as fructose, maltose, etc.

The plasticiser(s) preferably constitute from 0.0 to 80% w/w of the total composition.

- 15 The whitening agent is preferably peroxide based. Any peroxide compound may be used, but especially preferred peroxides include hydrogen peroxide and/or urea peroxide.

The whitening agent preferably constitutes from 0.1% to 50% w/w of the present invention.

- 20 Advantageously, the use of peroxide alone as the whitening agent gives rise to a composition that is especially stable and therefore has a long shelf life. This is in contrast to whitening agents such as perchlorates which are present in known tooth-whitening compositions.

The composition described herein may comprise further additional ingredients such as stabilisers, humectants, thickeners, preservatives and processing aids - colourants, flavourings and mixture thereof. The processing aids include silicone based components such as dimethicone.

5 In use, a strip of the film of the present invention is applied to the teeth each morning and each night for 30 days. It might be expected that the application of such a product without a carrier or backing material would irritate or redden the tissues of the mouth, surprisingly it displays no such irritation. Such applications are well below the SCCNFP proposed guidelines for exposure to components such as hydrogel
10 peroxide at 50mg / day.

The present invention will now be described further by way of example only.

| Material | Amount (% w/w) | Function |
|-----------------------|----------------|--------------------------------|
| Hydroxyethylcellulose | 75% | Film forming polymer/thickener |
| Hydrogel Peroxide | 5.5% | Bleaching agent |
| Propylene Glycol | 5% | Humectant |
| Glycerol | 12% | Humectant |
| Sodium Stannate | 2% | Stabiliser |
| Methylparaben | 0.25% | Preservative |
| Dimethicone | 0.25% | Processing aid |

15 An additional 3000% of purified water is used in the manufacture of this example. The water added to a low shear mixer and circulated. The methylparaben is dissolved in the water and then the mixture is cooled to below 25c. At this point the other ingredients (excluding the hydroxyethylcellulose) are added and mixed for a further 10 minutes. The hydroxyethylcellulose is added slowly to produce a homogenous mixture with a viscosity of in the region of 50,000 cps.

The resulting polymer solution is cast onto a carrier surface and dried under heat, UV or IR to give a soft flexible water soluble film which can then be cut into pieces for application and whitening of the teeth.

It is of course to be understood that the invention is not intended to be
5 restricted to the details of the above embodiments which are described by way of example only.

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